Baha®
Vistafix®

Osscora™ Surgical Set

Instructions for Use

Model no. 91051/91052/91053

Hear now. And always

Cochlear™

Symbols

Warning
Risk of injury.

Attention
Important notes to prevent damage occurring.

General explanations
Without risk to persons or objects.

Thermo washer
Disinfectable.

Sterilisable
Up to the stated temperature.

Only for USA
Caution: Federal law (USA) restricts this device to sale by or on the order of a medical practitioner.

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1. Introduction

For your safety and the safety of your patients
These Instructions for Use explain how to use your Cochlear product. However, we must also warn against possible hazardous situations. Your safety, the safety of your team, and of course, the safety of your patients is of paramount importance to us.

It is therefore essential to read the safety notes on pages 5 to 7.

Intended use
Osscora surgical set with contra-angle handpiece is intended to be used for Baha® and/or Vistafix® surgery including:

- Dermatome use
- Drilling
- Thread cutting
- Implant placement and removal

Osscora surgical set with contra-angle handpiece is intended to be used in operating rooms and to be used by trained surgeons and operating room staff.
Osscora surgical set is CE-marked according to Medical Device Directive 93/42/EEC.

Responsibility of the manufacturer
Cochlear Bone Anchored Solutions AB can only accept responsibility for the safety, reliability and performance of the Osscora surgical set when there is compliance with the following directions:

- The Osscora surgical set must be used in accordance with these Instructions for Use.
- The Osscora surgical set has no components which can be repaired by the user. Assembly, modifications or repairs must be undertaken by authorised personnel only.
- The electrical installation at the premises must comply with the regulations applicable in your country.
- Unauthorised opening of the equipment invalidates all claims under warranty and any other claims.

2. Safety notes

Please ensure that you carry out the following instructions:

- Only fit the contra-angle handpiece when the motor is at a complete standstill.
- Never touch rotary instruments which are still rotating.
- Never touch the chuck mechanism of the contra-angle handpiece while it is still running.
- Always ensure correct operating conditions and that adequate cooling is delivered.
- Avoid overheating at the treatment site.

Inappropriate use
Improper use, in addition to incorrect assembly, installation, modification or repairs of the Osscora surgical set or non-compliance with our instructions invalidates all claims under warranty and any other claims.

Cardiac pacemaker function
Use of the Osscora surgical set involves the generation of magnetic fields, which are below the interference threshold limit according to EN 50061 Ad1. Even under adverse conditions, there is no likelihood of serious harm to the patient. The Osscora surgical set is designed for the intermittent operating mode S3 with an operating time of 4 minutes and a pause time of 10 minutes.

2. Safety notes

Danger zones M and G

In accordance with IEC 60601-1 /UL 60601-1, the control unit is not suitable for use in potentially explosive atmospheres or with potentially explosive mixtures of anaesthetic substances containing oxygen or nitrous oxide.

Control unit

The control unit is classed as "conventional equipment" (closed equipment without protection against the ingress of water).

The Osscora surgical set control unit is designed only to be used with the Osscora contra-angle handpiece.

Motor and foot control

The motor and foot control are approved for use in zone M (AP).

Please note that at low speeds, it is more difficult to determine that the motor is running.

2. Safety notes

Mains cable
Only connect to an earthed socket outlet.

Power failure
In the event of a power failure, if the control unit is switched off, or when alternating between programs, the last values set are saved and reactivated on power-up.

System failure
A total system failure of the Osscora surgical set does not constitute a critical fault.

Intermittent operating mode S3 (4min/10min)
When there is a current consumption of max. 0.8 A for 91051 and 91052 and 1.6 A for 91053 (with pump switched on), the permissible relative load time is 4 minutes to 10 minutes pause time.

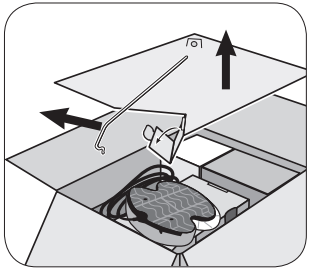
Coolant
The Osscora surgical set is designed for use with physiological saline solution. Use only suitable irrigation fluids and comply with the medical data and instructions from the manufacturer. Use the supplied irrigation tubing set or accessories supplied by Cochlear. Coolant bottle or coolant bag can be obtained from a pharmacist.

Sterility of irrigation tubing set
Sterile irrigation tubing sets are supplied with the equipment. These irrigation tubings are disposable articles and must be thrown away after each treatment!

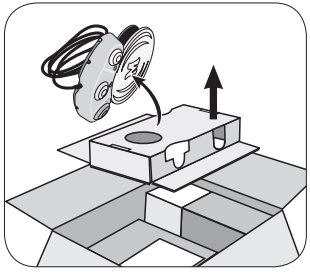
Please note the expiry date and the relevant regulations for disposal of irrigation tubing.

Rotational energy
Fast deceleration of the bur can, at times, cause the selected torque to be overloaded as a result of the rotational energy stored in the drive system.

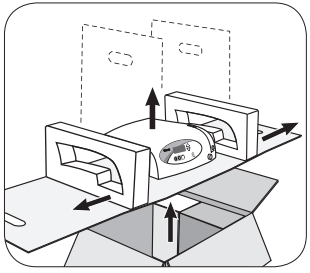
3. Unpacking



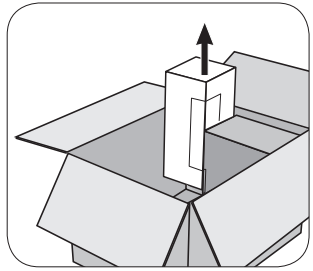
❶ Lift out insert with stand.



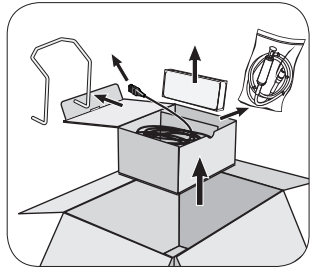
❷ Remove foot control and insert.



❸ Lift out insert with control unit.



❹ Remove irrigation tubing set.



❺ Remove carton containing motor, mains cable, handle and contra-angle handpiece.

The packaging is environmentally friendly and can be disposed of by industrial recycling companies. However, we recommend that you keep the original packaging.

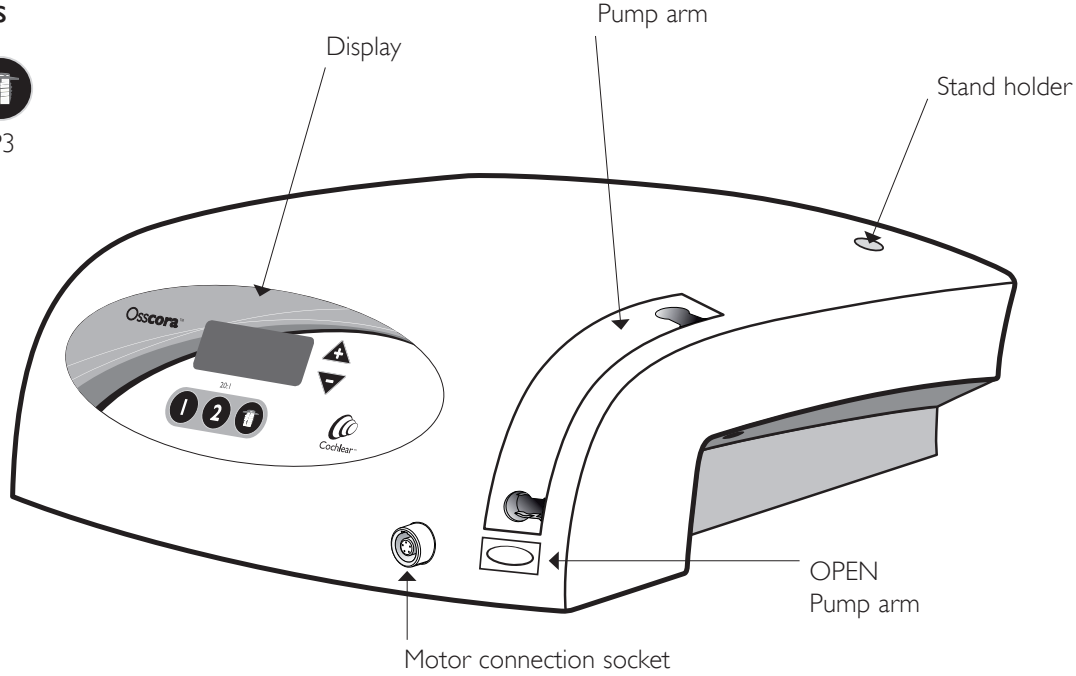
4. Equipment supplied

91051 Osscora surgical set **230 V (Europe)**	**91052 Osscora surgical set** **230 V (Asia Pacific)**	**91053 Osscora surgical set** **115 V**
Control unit, 230 V	Control unit, 230 V	Control unit, 115 V
Foot control S-N1	Foot control S-N1	Foot control S-N1
Motor with 3,5 m cable incl. motor protective cover, locking pins (2 pcs) and clips (10 pcs)	Motor with 3,5 m cable incl. motor protective cover, locking pins (2 pcs) and clips (10 pcs)	Motor with 3,5 m cable incl. motor protective cover, locking pins (2 pcs) and clips (10 pcs)
Osscora contra-angle handpiece	Osscora contra-angle handpiece	Osscora contra-angle handpiece
Irrigation tubing set (6 pcs)	Irrigation tubing set (6 pcs)	Irrigation tubing set (6 pcs)
Mains cables (4 pcs) (Europe) (UK, IRL) (CH) (DK)	Mains cables (3 pcs) (AUS, NZ) (Europe) (UK, IRL)	Mains cable (1 pcs) (USA, CAN, JAP)
Stand	Stand	Stand

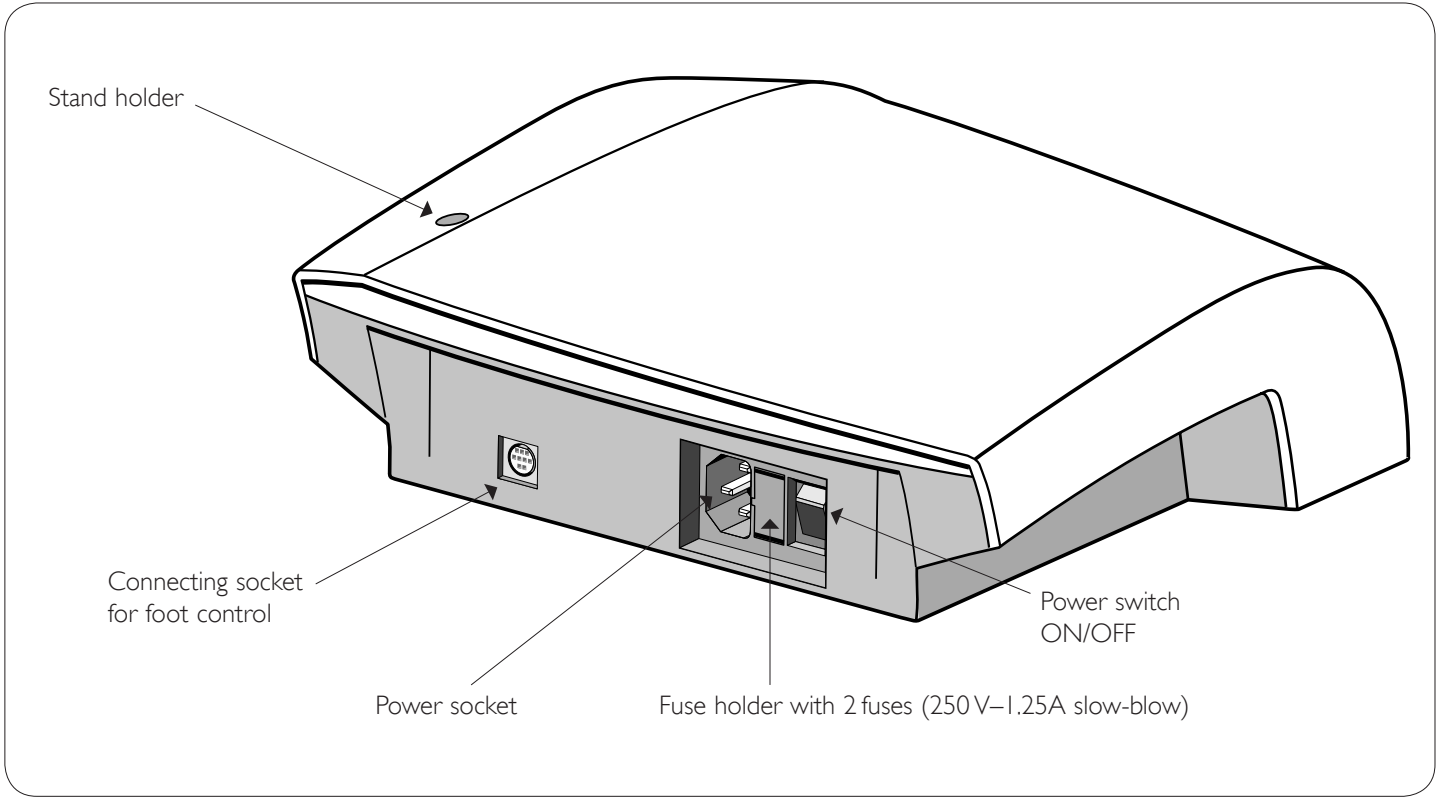
5. Description of front panel

Program buttons

P1 P2 P3



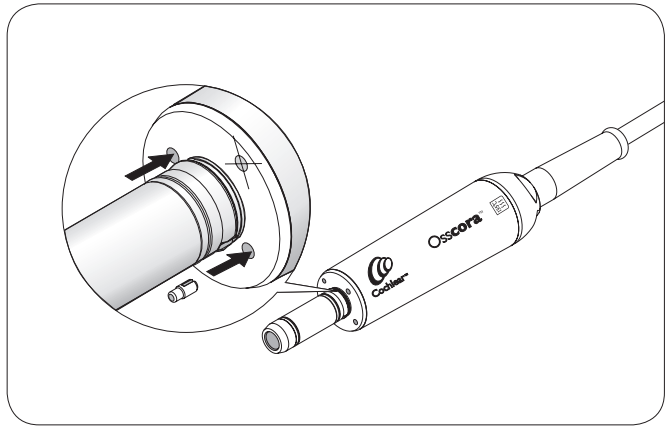
6. Description of rear panel



7. Description of motor with cable

The motor may not be dismantled!
The motor bearings are lubricated for life. No oil lubrication or other maintenance is necessary.

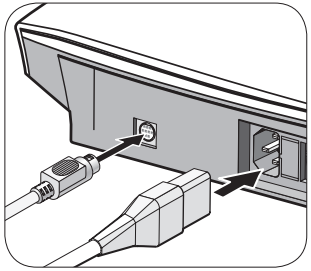
To prevent the instrument on the motor attachment from turning during the transmission, the locking pin supplied can be pushed into one of the two holes (see illustration).



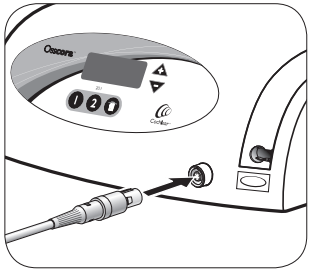
Test run

– Start the motor.
– If you observe dysfunctions (e.g. vibrations, unusual noise, overheating, coolant supply failure or leakage) contact your service agent. For details, please contact your local Cochlear office.

8. Starting operation–General

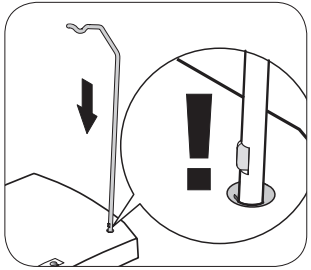


1 Connect the mains cable and foot control.



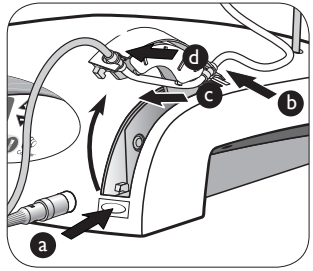
2 Connect the motor cable.

Note the positioning.

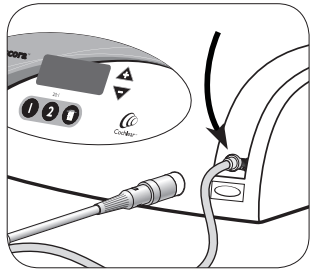


3 Insert the stand.

Note the positioning.

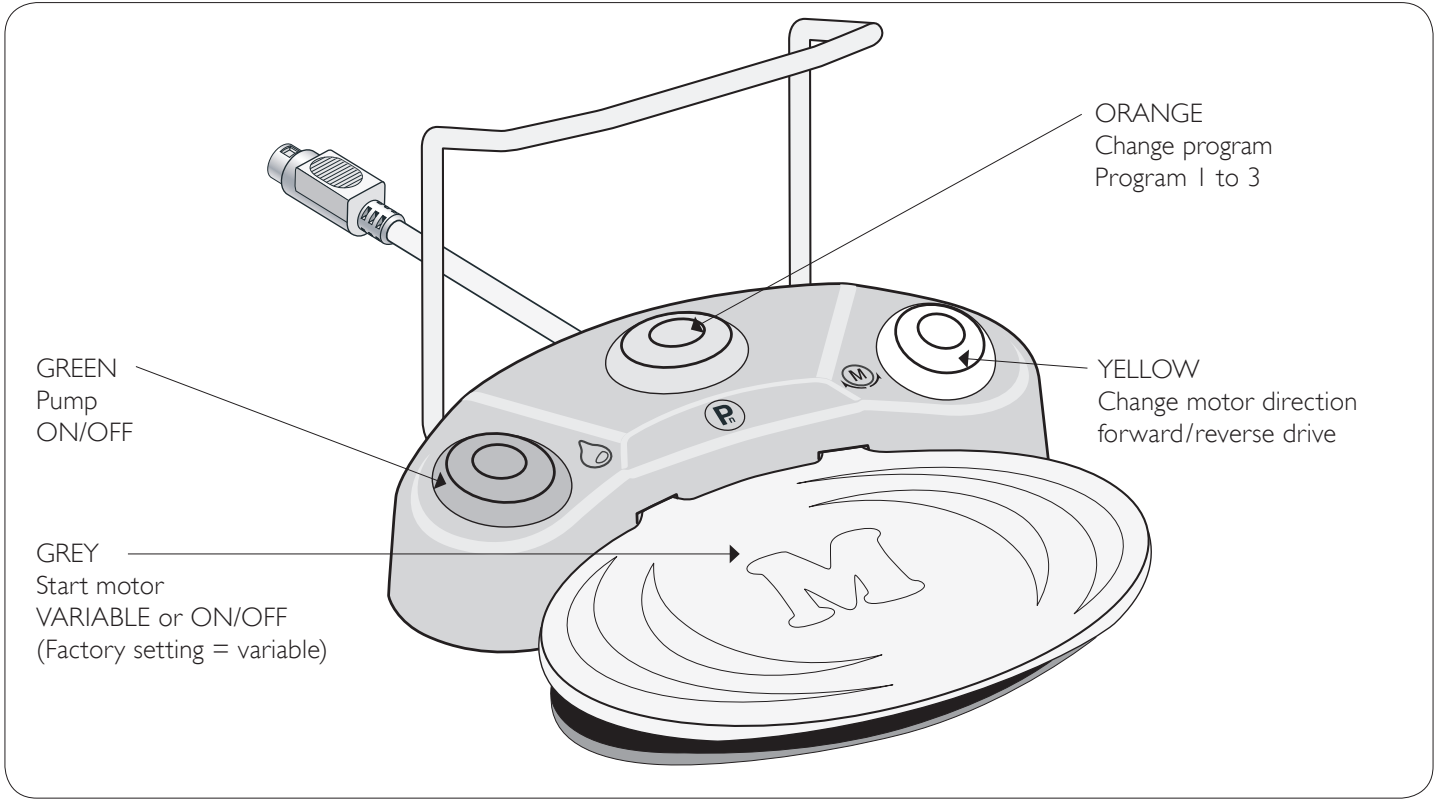


4 Fit the irrigation tubing set.



5 Close pump arm.

9. Starting operation–Foot control



9. Starting operation–Foot control

Changing program
The programs 1–3 can be selected in ascending sequence by operating the ORANGE button.

When changing from program 3 to program 1, a longer confirmation signal is heard.

With each program change, the motor direction is automatically set to forward operation.

Pump ON/OFF
Only when the motor is stationary can the pump be switched on or off by operating the GREEN button of the foot control. When pump operation is active, the pump symbol appears on the display.

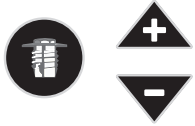
Reverse operation
You can switch between forward and reverse operation by pressing the YELLOW button. On selecting reverse operation, an audible signal can be heard and the selected program button flashes. Before the motor starts in reverse operation, 3 audible warning signals are given.

9. Starting operation–Foot control

To change from VARIABLE to ON / OFF

Keep program button P3 depressed throughout this procedure!

❶ Press P3 for approx. 4 seconds.



❷ Keep P3 depressed and simultaneously press PLUS and MINUS.

❸ Keep P3 depressed and carry out adjustment.

01 = VARIABLE (factory setting)–Press PLUS button.

00 = ON/OFF–Press MINUS button.

After changeover the program button P3 illuminates and is active!

10. Factory settings

Factory settings P1–P3	**P1**	**P2**	**P3 Forward**	**P3 Reverse**
Factory setting rpm	2000	2000	15	30
Adjustable range rpm	15–2000	15–2000	–	–
Motor direction	Forward	Forward	Forward	Reverse
Pump	Off	On	Off	Off
Factory setting Ncm	Max.	Max.	20	20
Adjustable range Ncm	–	–	5–50	5–50
Intermediate stage Ncm	–	–	32	32

10. Factory settings

Reset factory settings

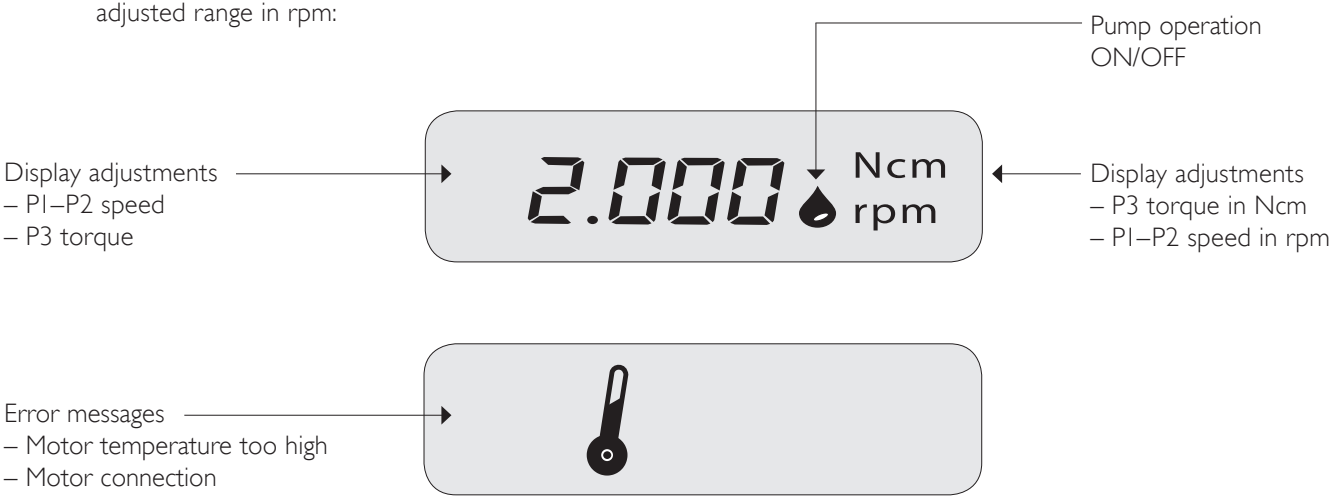
Factory setting always starts with program 1 (P1).

1. Switch off the control unit.
2. Keep P1 depressed and simultaneously switch on the control unit.
3. Keep P1 depressed as long as on the display the adjustment "DE FAU" appears.

11. Control unit operation

Changing the program (P1–P3)

Activate the required program (P1–P3) by pressing the corresponding program button. During selection an audible signal can be heard and the program button is illuminated. On the display the selected program appears with the adjusted range in rpm:



11. Control unit operation

Changing the speed (P1–P2)

Keeping PLUS/MINUS depressed activates the repeat function and the values are continuously increased/decreased.

Press program button (P1–P2).

Increase speed

Decrease speed

11. Control unit operation

Changing the torque (P3)

Adjustable range from 5 up to 50 Ncm, intermediate stage 32 Ncm. Keeping PLUS/MINUS depressed activates the repeat function and the values are continuously increased/decreased.

When changing from 5 to 50 Ncm and 50 to 5 Ncm, a longer confirmation signal is heard.

When the adjustable torque in the forward/reverse drive mode is reached, the motor switches off automatically.

Press P3.

Increase torque in 5-Ncm-steps

Decrease torque in 5-Ncm-steps

11. Control unit operation

Changing the coolant flow (P1–P3)

Factory setting 80%. Adjustable range 65%, 80% and 100%. Depressing PLUS/MINUS the values are continuously increased/ decreased.

Keep program button P2 depressed throughout this procedure!

Keep P2 depressed for approximately 4 seconds (the adjusted coolant flow rate appears).

Keep P2 depressed and press PLUS button to increase flow rate.

Keep P2 depressed and press MINUS button to decrease flow rate.

After adjustment, the program button P2 illuminates and is active!

12. Error messages

Error No.	Description	Remedy
00	Electronics overheating–safety shutdown	Switch off the equipment, allow to cool for at least 10 minutes, then restart
01	Electronics overloaded	Switch off the equipment and then restart
07	Foot control error–initialising	Switch off the equipment, restart, do not actuate foot control when switching on
09	Foot control error	Switch off the equipment, check connection of the foot control, then restart
19	Run limiting control	Switch off the equipment and restart
99	System failure	Switch off the equipment and restart
	Motor temperature too high	Switch off the equipment, allow motor to cool for at least 10 minutes, then restart
	Motor connection–safety shutdown	Switch off the equipment, check motor connection, then restart

12. Error messages

If one of the error messages described above cannot be rectified by switching off the Osscora surgical set and then switching it on again, the equipment must be checked by a service agent. For contact details, please contact your local Cochlear office.

If a total failure of the equipment occurs caused by external circumstances, the equipment must be switched off and then on again.

13. Disinfection, cleaning, sterilisation

Follow your country-specific directives, standards and guidelines for cleaning, disinfection and sterilisation.

- Wear protective clothing.
- Clean and disinfect the motor **immediately after every treatment.**
- Sterilise the motor following cleaning and disinfection.

Control unit, foot control

Pre-disinfection

- If heavily soiled: Clean first with disinfectant cloths. Only use disinfectants that have no protein-fixing effects.

Manual cleaning and disinfection

The front panel of the control unit and the foot control are sealed and may be wiped clean.

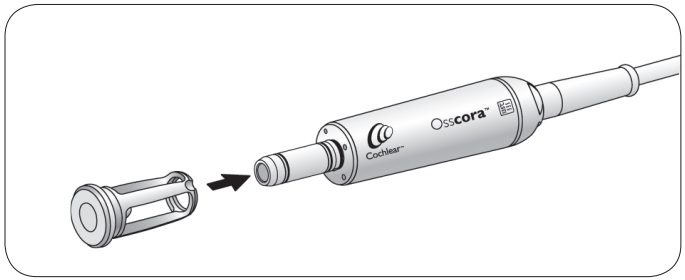
- Disinfection with surface disinfectants, wiping disinfection is recommended.
- Use only surface disinfectants which do not contain chlorine and which are certified by officially recognised institutes. **For USA:** Use EPA registered surface disinfectants.
- Note the manufacturer's specifications for the use of the surface disinfectants.

13. Disinfection, cleaning, sterilisation

Motor with cable

Do not twist and kink the motor cable! Do not coil it too tightly! This instruction is not necessary when a sterilisation cassette is utilised (optional accessory).

Before disinfection and cleaning push the motor protective cover onto the motor attachment!



Pre-disinfection

– If heavily soiled: Clean first with disinfectant cloths. Only use disinfectants that have no protein-fixing effects.

Manual cleaning

– Rinse under demineralised water (< 38 °C) with the aid of a brush (brush is not recommended in U.K.)
– Then remove any liquid residues (absorbent cloth, blow dry with compressed air).

Disinfection

– Disinfect with surface disinfectants. Wiping disinfection is recommended.
– Use only surface disinfectants which do not contain chlorine and which are certified by officially recognised institutes.
For USA: Use EPA registered surface disinfectants.
– Note the manufacturer's specifications for the use of the surface disinfectants.

13. Disinfection, cleaning, sterilisation

Sterilisation and storage

Cochlear recommends sterilisation according to EN 13060 and EN 285, class B.

Sterilisation and storage

– Note the instructions of the steriliser manufacturer.
– Clean and disinfect before sterilising.
– Wrap the motor and the accessory in sterile goods packing according to EN 868-5.
– Make sure that you only remove dry sterile goods.
– Store sterile goods dust-free and dry.

Approved sterilisation procedures

Follow your country-specific directives, standards and guidelines.

– Steam sterilisation with sterilisers in accordance with EN 13060 or EN 285, class B.

Sterilisation holding time: Minimum of 3 minutes at 134 °C (273.2 °F)

or

– Steam sterilisation with sterilisers in accordance with EN 13060 or EN 285, class S.

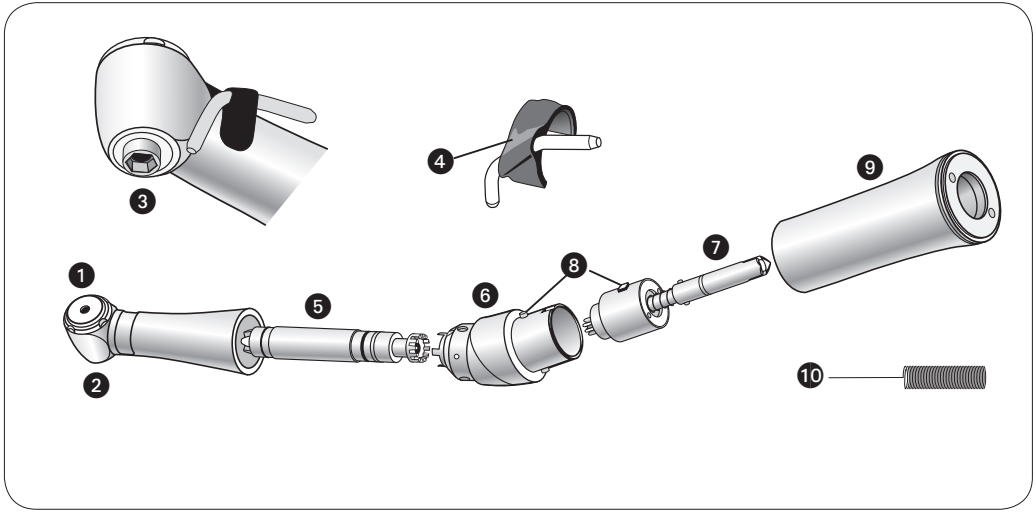
The steriliser manufacturer must give their express approval for the sterilisation of motors.
Sterilisation holding time: Minimum of 3 minutes at 134 °C (273.2 °F).

For sterilisation in sterilisers with a drying program we recommend that you remove the motor protective cover.

14. Osscora contra-angle handpiece

Product description
Osscora contra-angle handpiece

1. press-button
2. head
3. hexagon chucking system
4. spray clip
5. middle gear
6. knee
7. lower shaft
8. locking pin
9. sheath
10. nozzle cleaner



14. Osscora contra-angle handpiece

Before use–safety notes

CAUTION:

- If using a Dermatome, please note the Osscora contra-angle handpiece is designed for use with the Baha Dermatome for Osscora only. It must not be used with any other Dermatome model.
- This contra-angle handpiece is only intended for use with Osscora surgical set for Baha and Vistafix surgery.

Prior to initial use:

- Please read the section on hygienic maintenance, page 34–43.
- Lubricate the contra-angle handpiece.
- Sterilise the contra-angle handpiece, nozzle cleaner and spray clip.
- Check contra-angle handpiece for damage and loose parts prior to use.
- Always ensure correct operating conditions and cooling function prior to use.

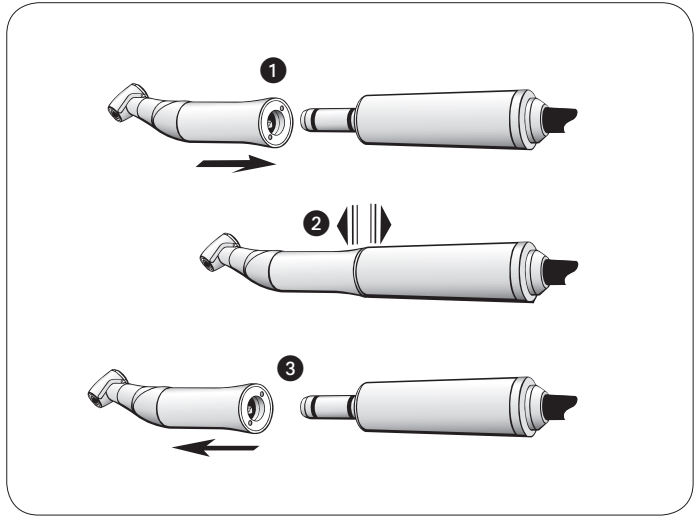
Only assemble components with corresponding type and serial number. Exception: components may be changed at service or repair–these may have a new serial number.

14. Osscora contra-angle handpiece

Operation

Assembly and removal
Do not assemble/remove the contra-angle handpiece during the operation!

1. Push the contra-angle handpiece onto the motor.
   – Use a rotational lock between motor and instrument: see page 12.
2. Check that the motor and handpiece are securely attached.
3. Remove the contra-angle handpiece from the motor by pulling in an axial direction.



14. Osscora contra-angle handpiece

Operation

Rotary instruments

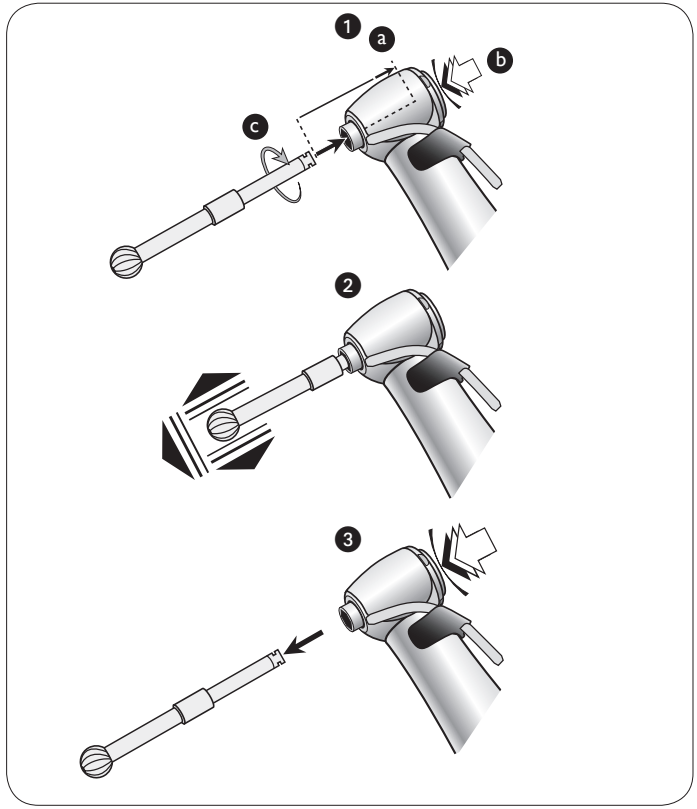
– Use only rotary instruments that are in perfect condition and be careful when the rotary instrument is rotating.
– Insert rotary instruments only when the contra-angle handpiece is stationary.
– Do not activate the press-button of the contra-angle handpiece during operation. This leads to detachment of the rotary instrument and makes the head of the contra-angle handpiece hot.

To change rotary instrument in the Osscora contra-angle handpiece

1. Insert the rotary instrument into the contra-angle handpiece until back stop (a). Activate press-button (b) and turn the rotary instrument until it engages (c).

2. Check secure location by applying slight axial tension.

3. Remove the rotary instrument by pushing the press-button.



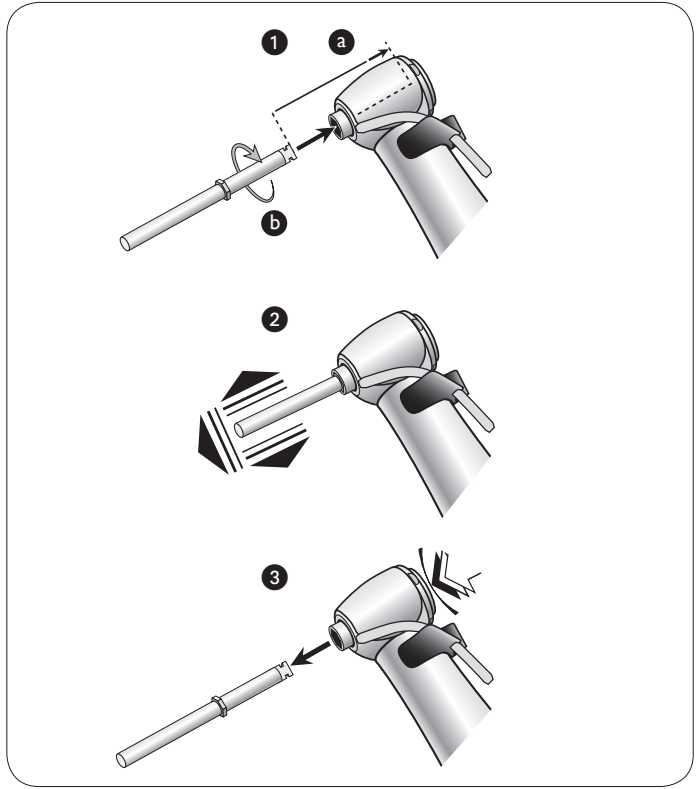
14. Osscora contra-angle handpiece

Operation

To change rotary instrument with hexagon in the Osscora contra-angle handpiece

1. Insert the rotary instrument into the contra-angle handpiece until back stop (a) and turn until it engages (b).
2. Check secure location by applying slight axial tension.
3. Remove the rotary instrument by pushing the press-button.

Please contact your local Cochlear office for how to get an applicable rotary instrument with hexagon.



14. Osscora contra-angle handpiece

Operation

Test run

– Insert rotary instrument.
– Start the contra-angle handpiece.
– If you observe problems (e.g. vibrations, unusual noise, overheating, coolant supply failure or leakage) contact your service agent. For contact details, please contact your local Cochlear office.

14. Osscora contra-angle handpiece

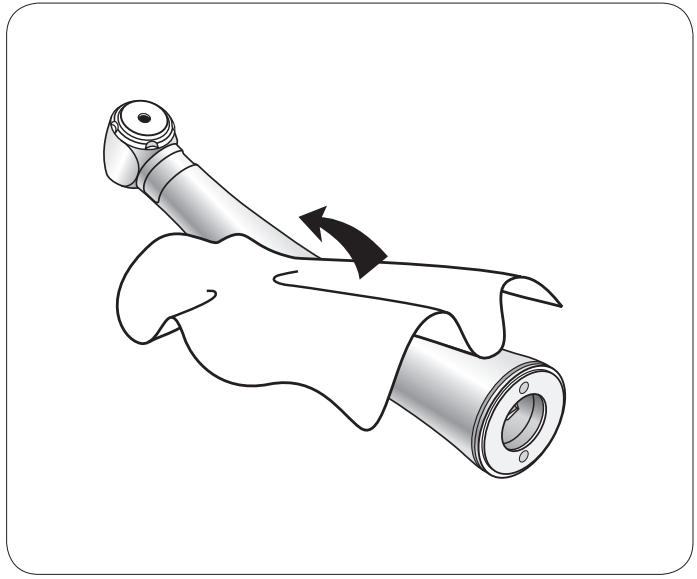
Hygienic maintenance

Follow your country-specific directives, standards and guidelines for cleaning, disinfection and sterilisation.
– You can process the contra-angle handpiece manually or automatically.

– Wear protective clothing.
– Remove the rotary instrument.
– Remove the contra-angle handpiece from the motor.

– Clean and disinfect the disassembled contra-angle handpiece **immediately after every treatment,** to flush out any liquid residues (such as blood, etc.) and to prevent settling on the internal parts.

– Sterilise the contra-angle handpiece following manual or automatic cleaning, disinfection and lubrication.

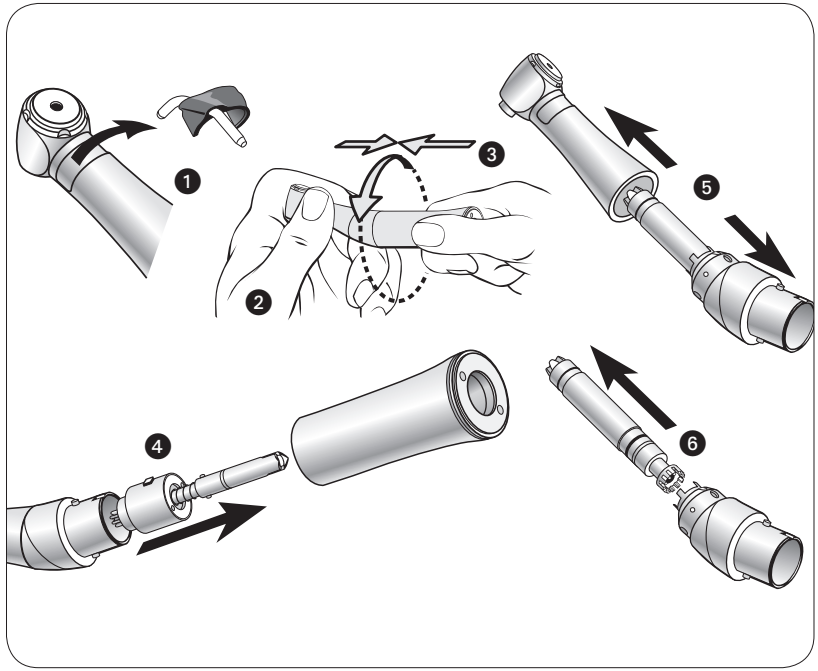


Pre-disinfection
– If heavily soiled: Clean first with disinfectant cloths. Only use disinfectants that have no protein-fixing effects.

14. Osscora contra-angle handpiece

Disassemble Osscora contra-angle handpiece

1. Remove the spray clip.
2. Hold the head firmly with one hand.
3. Press sheath gently against knee. At the same time turn off the sheath from the knee.
4. Remove the shaft.
5. Remove the knee.
6. Remove the middle gear from the knee.

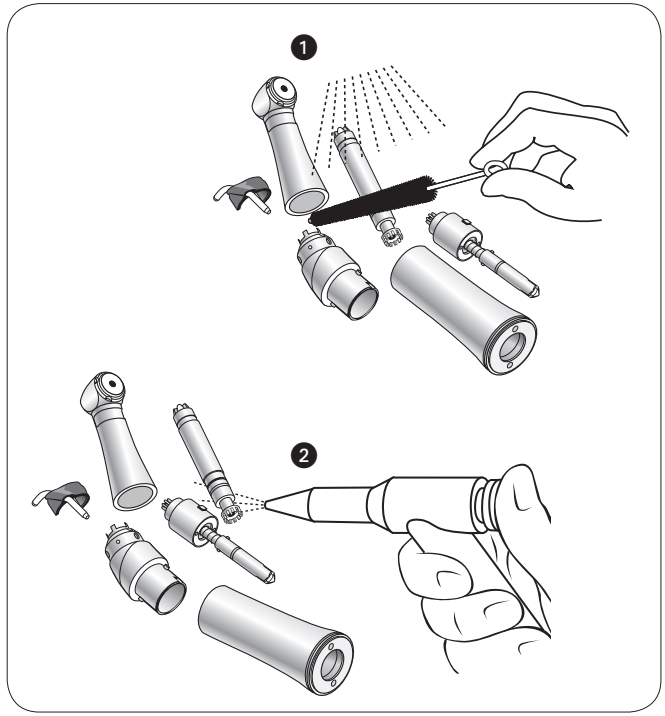


14. Osscora contra-angle handpiece

Manual cleaning

1. Rinse under demineralised water (< 38 °C) with the aid of a brush (not recommended in U.K.).
2. Then remove any liquid residues (absorbent cloth, blow dry with compressed air).

Do not place the contra-angle handpiece in liquid disinfectant or in an ultrasonic bath.



14. Osscora contra-angle handpiece

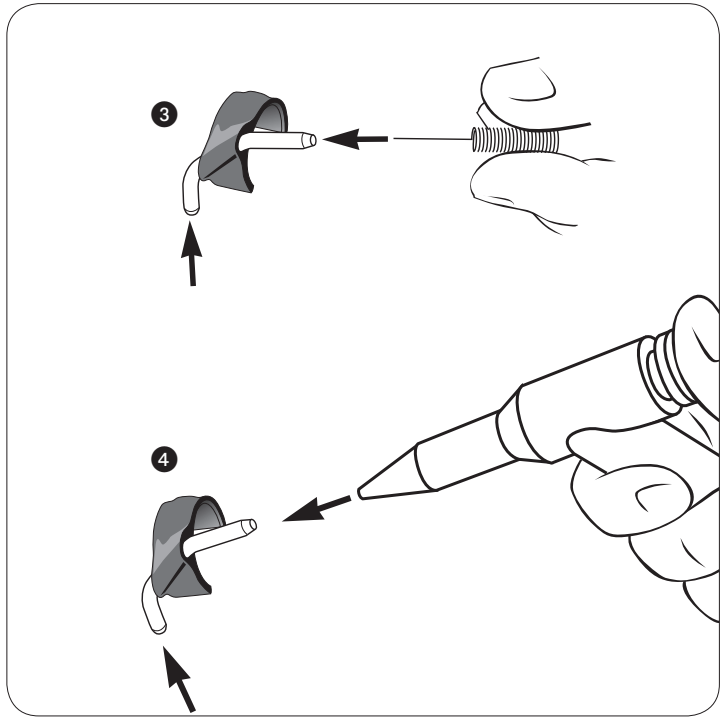
Clean external coolant tubes

3. Clean coolant outlet carefully with the nozzle cleaner to remove dirt and deposits.
4. Blow through the coolant tube and coolant outlet with the air syringe.

In the case of a clogged up spray nozzle or coolant tube contact your service agent. For details, please contact your local Cochlear office.

The removable spray clip can be cleaned in an ultrasonic bath.

Reassemble the contra-angle handpiece (serial numbers on individual parts must be identical). Exception: Components may be changed at service or repair - these may have a new serial number.

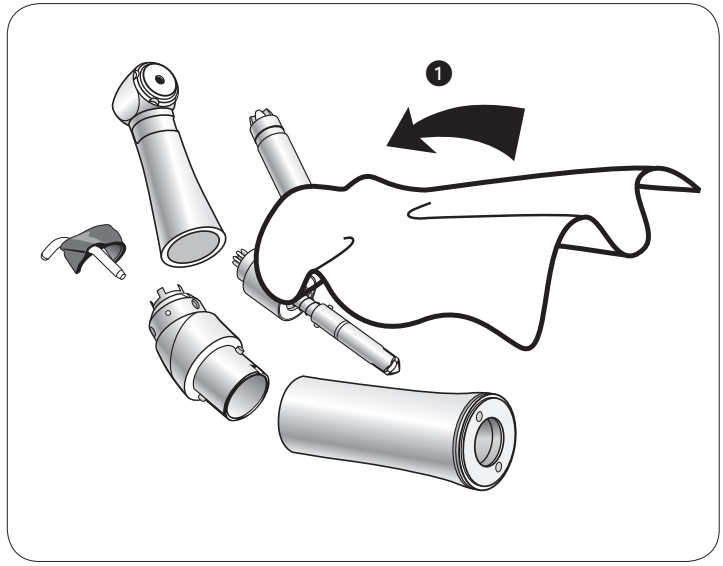


14. Osscora contra-angle handpiece

Manual disinfection

– Disinfect with surface disinfectants.
  ❶ Wiping disinfection is recommended.
– Use only surface disinfectants which do not contain chlorine and which are certified by officially recognised institutes.
  For USA: Use EPA registered surface disinfectants.
– Note the manufacturer's specifications for the use of the surface disinfectants.

After manual cleaning, disinfection and lubrication you must carry out a final sterilisation (wrapped) in the class B or S steam steriliser (according to EN 13060 or EN 285).



14. Osscora contra-angle handpiece

Mechanical cleaning and disinfection internal and external

Lubricate the contra-angle handpiece immediately after thermo washer disinfection.

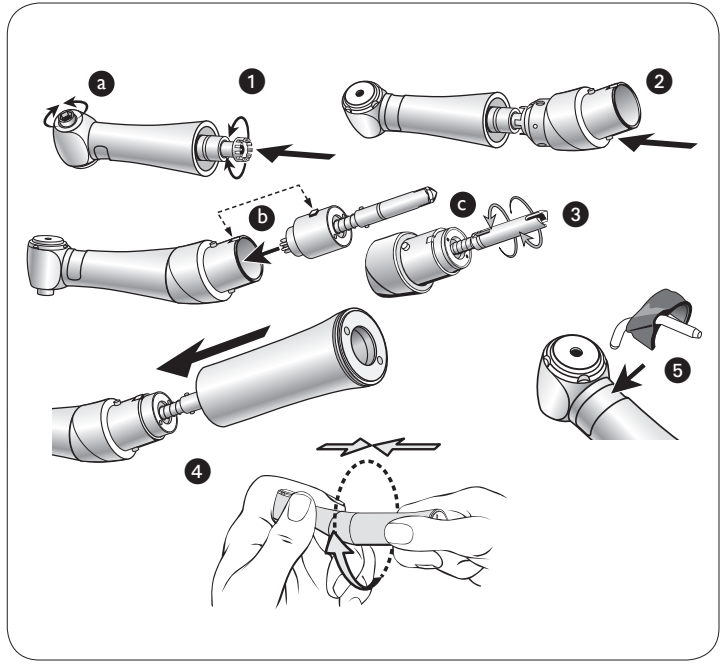
A contra-angle handpiece with this symbol can be cleaned and disinfected in a thermo washer disinfector.

– Cochlear recommends processing with a thermo washer disinfector.
– Note the manufacturer's specifications on equipment, cleaning agents and detergents.

14. Osscora contra-angle handpiece

Reassemble Osscora contra-angle handpiece

1. Insert the middle gear into the contra-angle head. Check free running of the chucking system (a).
2. Insert the knee (4 positions are possible) onto the contra-angle head until it engages.
3. Put the shaft in the knee and mind the position of the rotational lock (b). Check free running rotation (c).
4. Press the sheath firmly against the knee and turn until it engages.
5. Attach the spray clip.



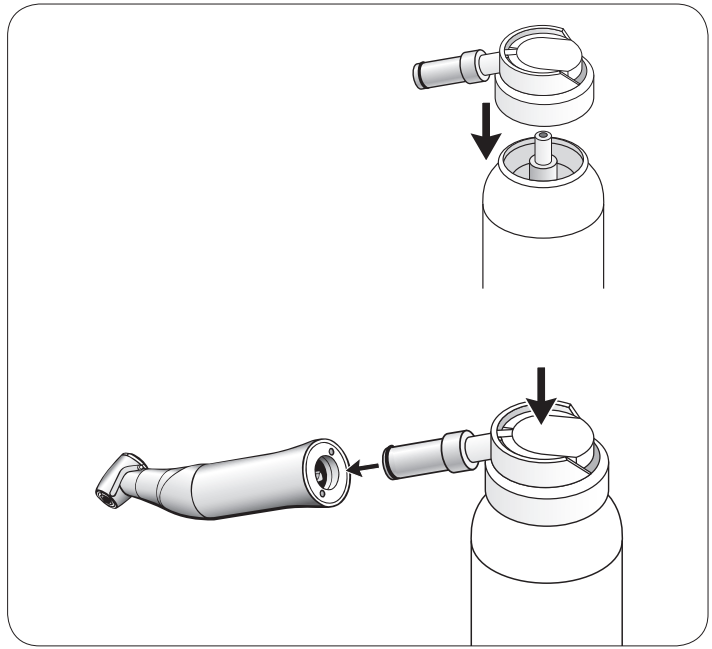
Only assemble components with corresponding type and serial number. Exception: components may be changed at service or repair - these may have a new serial number.

14. Osscora contra-angle handpiece

Daily oil service only with W&H Service Oil F1, MD-400.
For oil service, W&H Service Oil F1, MD-400 is recommended. For details on how to purchase this, contact your local Cochlear office.

– Follow the Instructions for Use of the oil spray can.

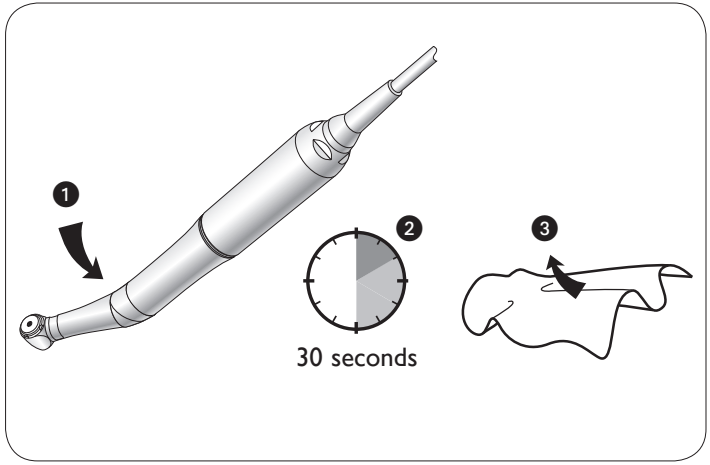
Recommended lubrication cycles
– Essential after every internal cleaning.
– Before each sterilisation.



14. Osscora contra-angle handpiece

Test run following oil service

1. Place the contra-angle handpiece with the head, downwards.
2. Start the contra-angle handpiece for 30 seconds to remove excess oil. Start at the minimum speed and increase to the maximum speed within 5 to 10 seconds.
   - Repeat the complete hygiene and maintenance process at any sign of dirt re-emerging.
3. Wipe contra-angle handpiece with gauze or soft cloth.

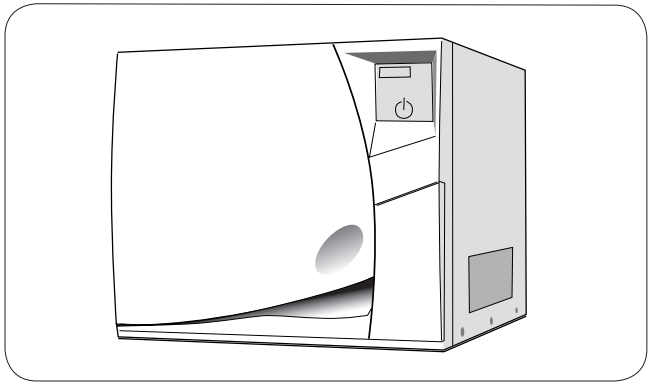


14. Osscora contra-angle handpiece

Sterilisation and storage

Cochlear recommends sterilisation according to EN 13060 or EN 285, class B.

– Note the instructions of the steriliser manufacturer.
– Clean, disinfect, reassemble and lubricate before sterilising.
– Wrap the contra-angle handpiece and the accessory in sterile goods packing according to EN 868-5.
– Make sure, that you only remove dry sterile goods.
– Store sterile goods dust-free and dry.



Approved sterilisation procedures

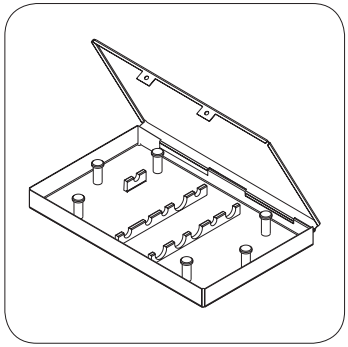
Follow your country-specific directives, standards and guidelines.

– Steam sterilisation with sterilisers in accordance with EN 13060 or EN 285, class B.
Sterilisation holding time: Minimum of 3 minutes at 134 °C (273.2 °F)

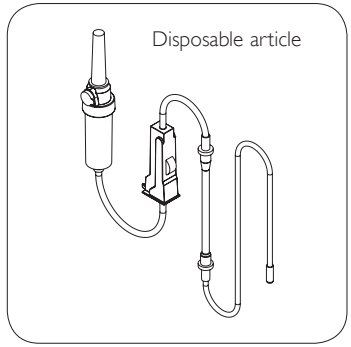
or

– Steam sterilisation with sterilisers in accordance with EN 13060 or EN 285, class S.
The steriliser manufacturer must give their express approval for the sterilisation of contra-angle handpieces.
Sterilisation holding time: Minimum of 3 minutes at 134 °C (273.2 °F).

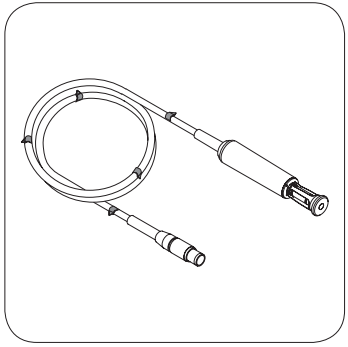
15. Osscora accessories



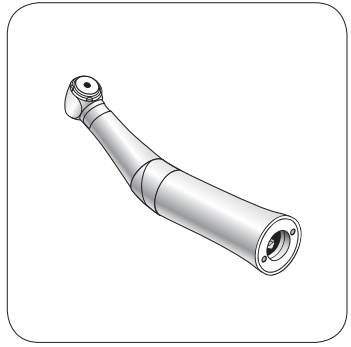
91102
Sterilisation cassette.



91061
Irrigation tubing set
3,8 m (6 pcs).



91054
Osscora motor
with 3,5 m cable.



91050
Osscora contra-angle
handpiece.

16. Servicing

Regular checking of Osscora surgical set and accessories

Regular servicing of function and safety of the Osscora surgical set including the accessories is necessary and should be carried out at least once every three years, unless shorter intervals are prescribed by law. The inspection must be undertaken by a qualified organisation and needs to include the following procedures:

– Visual inspection for outside damage.
– Measurement of enclosure leakage current.
– Measurement of patient leakage current.
– Visual inspection of internal components and electronic boards on suspicion of safety interference, e. g. mechanical damage of the enclosure or indicators for overheated or burned (electronic) components.

We recommend that only authorised personnel undertake this servicing and checking. For details, please contact your local Cochlear office.

16. Servicing

Motor and cable
The standard ISO 11498 stipulates a durability of at least 250 sterilisation cycles. In the case of the motor with cable from Cochlear we recommend that you carry out a regular servicing after 500 sterilisation cycles, or one year.

Repairs
If a defect occurs, always return all the equipment, due to the fact that with motor malfunctions, an inspection of the electronic controls is also necessary!

Returns
– Refer all questions to your local Cochlear office.
– Always return equipment in the original packaging!

– Do not coil the cable around the motor and do not twist or kink the motor cable! (Risk of damage).

17. Technical data

	91051 / 91052	91053
Supply voltage:	220–240 V	100–130 V
Rated current:	0.1–0.8 A	0.2–1.6 A
Permitted voltage fluctuation:	± 10 %	± 10 %
Frequency:	50–60 Hz	50–60 Hz
Max. mechanical output power:	70 W	70 W
Max. torque on the motor:	5.5 Ncm	5.5 Ncm
Max. coolant in ml (with hose ø 6/4):	approx. 100 ml/min	approx. 100 ml/min
Fuses:	2x 250 V–1.25A slow-blow	2x 250 V–1.25A slow-blow
Operating mode:	S3 (4min/10min)	S3 (4min/10min)
Dimensions in mm (WxDxH):	252 x 254 x 90	252 x 254 x 90
Set weight in kg:	4.10	4.10

Classification according to § 5 of the General Specifications for the Safety of Medical Electrical Equipment according to IEC 60601-1/UL 60601-1:

Equipment of Protective Class II (type of protection against electric shock).

Type BF appliance (not suitable for intracardiac application).

Motor and foot control conform to Class AP according to IEC 60601-1/UL 60601-1 in danger zone M.

The foot control is watertight according to PX8, 1m depth of immersion, 1 hour (water-tight according to IEC 60529).

17. Technical data

Physical characteristics

Temperature in storage:	-20 °C (-4 °F) to +50 °C (+122 °F)
Air humidity in storage:	8 % to 80 % (relative) non-condensing at +40 °C (+104 °F)
Temperature in operation:	+10 °C (+50 °F) to +40 °C (+104 °F)
Air humidity in operation:	15 % to 80 % (relative) non-condensing at +40 °C (+104 °F)

Technical data Osscora contra-angle handpiece

Transmission ratio	20:1
Colour coding	green
Motor coupling according to standard	ISO 3964
Rotary instruments, EN ISO 1797-1 (Ø mm)	2,35*
Length (of rotary instr.) approved by Cochlear (mm)	max. 45**

Disposal of the Osscora surgical set equipment
The equipment contains many valuable materials. Therefore return your equipment for material recycling via the relevant public collection system.

Disposal of the foot control
When the foot control is to be scrapped, it must be disposed of in accordance with local regulations.

Warranty
As manufacturer, Cochlear Bone Anchored Solutions AB is liable for material or manufacturing defects within a warranty period of one year from the date of purchase. Only Cochlear products and accessories, or products and accessories approved by Cochlear, should be used with each other in order to ensure that the warranty is maintained.

*When having a torque higher that 30 Ncm on the rotary instrument you have to use hardened shafts (>50 HRC, > 520 HV) (risk of deformation).

** When using a longer rotary instrument the user must ensure by correct selection of the operating conditions, that there is no danger to the user, patient or third parties.

Copy for the user/customer

Certification of training

Essential for EU user/customer

The user has been trained in all functions of the Osscora surgical set in accordance with current Instructions for Use. Particular attention was shown to Safety notes, Disinfection, cleaning, sterilisation and Servicing.

Osscora surgical set.....

Type.....

Serial Number.....

Name of the user/customer.....

Clinic, Department.....

Address.....

Signature.....

Name of the instructor.....

Address.....

Date.....

Signature.....

Hear now. And always

Cochlear™

Certification of training

Essential for EU user/customer

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Osscora surgical set.....

Type.....

Serial Number.....

Name of the user/customer.....

Clinic, Department.....

Address.....

Signature.....

Name of the instructor.....

Address.....

Date.....

Signature.....

Cochlear™

Manufacturer:
Cochlear Bone Anchored Solutions AB
Konstruktionsvägen 14, SE-435 33 Mölnlycke, Sweden.
Tel +46 31 792 44 00, Fax: +46 31 792 46 95

Regional offices:
Cochlear Americas
400 Inverness Parkway, Suite 400, Englewood CO 80112, USA
Tel: +1 303 790 9010 Fax: +1 303 792 9025

Cochlear AG
European Headquarters, Margarethenstrasse 47, CH - 4053 Basel, Switzerland
Tel: +41 61 205 0404 Fax: +41 61 205 0405

Cochlear Ltd
(ABN 96 002 618 073) 14 Mars Road, Lane Cove NSW 2066, Australia
Tel: +61 2 9428 6555 Fax: +61 2 9428 6352

www.cochlear.com

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